

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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WARNER CHILCOTT LABORATORIES	:	
IRELAND LIMITED, <i>et al.</i> ,	:	<b>Civil Action Nos.</b>
	:	<b>08-6304 (WJM); 09-0228 (WJM);</b>
<b>Plaintiffs,</b>	:	<b>09-0469 (WJM); 09-1233 (WJM);</b>
	:	<b>09-2073 (WJM)</b>
<b>- vs -</b>	:	
	:	
	:	<b><u>OPINION</u></b>
IMPAX LABORATORIES, INC., <i>et al.</i> ,	:	
	:	
	:	
<b>Defendants.</b>	:	
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**THIS MATTER** comes before the Court as a result of Plaintiffs’ letter dated January 14, 2010, requesting a modification of the claim construction schedule; Defendants’ response dated January 15, 2010; and Plaintiffs’ reply dated January 21, 2010;<sup>1</sup> and it appearing that:

1. Plaintiffs have commenced five Hatch-Waxman patent infringement actions against a number of Defendants, including Impax Laboratories, Inc., Actavis Elizabeth, LLC, Sandoz, Inc., Mutual Pharmaceutical Company, and Mylan Pharmaceuticals, Inc. (collectively, “Defendants”), alleging infringement of United States Patent No. 6,958,161 (“the ‘161 patent”).<sup>2</sup> The ‘161 patent claims modified release preparations of doxycycline hyclate for treating bacterial infections, marketed under the brand name Doryx®.

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<sup>1</sup> The letters have not been filed on the Court’s electronic docket.

<sup>2</sup> The actions have been consolidated for pretrial purposes. See CM/ECF No. 60.

2. On October 20, 2009, the Court entered a pretrial scheduling order setting dates for, among other things, the exchange of preliminary proposed claim constructions and extrinsic evidence, and *Markman* submissions. See CM/ECF No. 66. The dates in the scheduling order were selected with the input of and, in most instances, consent of the parties.

3. By letter dated January 14, 2010, Plaintiffs requested what they call a “modest” revision to the claim construction schedule. Plaintiffs seek to expand the claim construction schedule to provide for an additional reply *Markman* brief, which is not provided for under the Court’s Local Patent Rules (the “Patent Rules” or the “Rules”), and to defer expert discovery until after the service of both opening and responding *Markman* briefs. The basis for Plaintiffs’ requests is their concern that Defendants may attempt to designate a previously undisclosed expert for claim construction purposes in connection with their responding *Markman* submission, and that they may not have an opportunity to depose any such expert under the terms of the Scheduling Order.

4. By letter dated January 15, 2010, Defendants objected to Plaintiffs’ request as premature, arguing that they do not intend to utilize an expert in their opening *Markman* submission and may, in fact, choose not to utilize an expert at all. Defendants’ letter also requested that the Court preclude Plaintiffs’ formulation expert, Dr. James McGinty, from submitting an expert declaration in connection with Plaintiffs’ *Markman* submissions due to Plaintiffs’ alleged failure to comply with the expert disclosure requirements of the Patent Rules. Plaintiffs replied to Defendants’ letter with a second letter dated January 21, 2010, opposing any restrictions on Dr. McGinty’s expert testimony and reiterating their request for a modification of the Scheduling Order.

5. The Scheduling Order Plaintiffs seek to amend is modeled on the Court's Local Patent Rules.

6. The Local Patent Rules govern "all civil actions filed in or transferred to this Court which allege infringement of a patent in a complaint, counterclaim, cross-claim, or third party claim, or which seek a declaratory judgment that a patent is not infringed, is invalid or unenforceable." L. Pat. R. 1.2.<sup>3</sup> The Patent Rules contain an entire section directed to claim construction proceedings, which is the issue now in dispute. See generally L. Pat. R. 4.

7. Local Patent Rule 4.2 is titled "Exchange of Preliminary Claim Constructions and Extrinsic Evidence." This Rule contemplates that, at the time the parties exchange their respective preliminary claim constructions, "each party shall also identify all references from the specification or prosecution history that support its preliminary proposed construction and designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art and testimony of all witnesses including expert witnesses. . . . [W]ith respect to all witnesses, including experts, the identifying party shall also provide a description of the substance of that witness' proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction." L. Pat. R. 4.2(b).

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The Patent Rules were made effective January 1, 2009. See L. Pat. R. 1.4. The rules apply prospectively to any patent actions commenced on or after that date. Id. It is within the Court's discretion to apply the rules retroactively to cases pending prior to January 1, 2009, after consulting with the parties. See id. The lead action in these consolidated cases was commenced prior to January 1, 2009. Nevertheless, the parties' joint discovery plan expressly references and incorporates the Patent Rules, and the Court has proceeded throughout this case, including in issuing its Scheduling Order, as though the Patent Rules would govern all five of these Hatch-Waxman actions. Thus, the Court continues to apply the Patent Rules to all of the consolidated cases.

8. Within 30 days after the parties exchange their preliminary claim construction submissions, the parties must “complete and file a Joint Claim Construction and Prehearing Statement” (the “Prehearing Statement”) and accompanying documents with the Court. See L. Pat. R. 4.3(a). This statement is required to contain, among other things:

- (b) ***Each party’s*** proposed construction of each disputed term, together with an identification of all references from the intrinsic evidence that support that construction, and an **identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party’s proposed construction, including . . . testimony of all witnesses including experts.**

- (e) Whether any party proposes to call one or more witnesses at the Claim Construction Hearing, the identity of each such witness, and for each witness, a summary of his or her testimony including, for any expert, each opinion to be offered related to claim construction.

L. Pat. R. 4.3(b), (e) (emphases added).

9. Thereafter, the parties have 45 days to file their opening *Markman* submissions and supporting documentation, including expert certifications. See L. Pat. R. 4.5(a). Expert discovery commences and concludes in the 30 day period following the opening *Markman* submissions. See L. Pat. R. 4.5(b). Thirty days after the close of expert discovery, and 60 days after the opening *Markman* submissions, responding *Markman* submissions, including responding expert certifications, are filed. See L. Pat. R. 4.5(c). The parties are then required to propose a claim construction schedule to the Court. See L. Pat. R. 4.6. There is no extensive period of discovery, and there are no reply *Markman* submissions. Even a *Markman* hearing itself is at the discretion of the Court. See id.

10. Plaintiffs seek to amend the Court's Scheduling Order (and the District's Local Patent Rules), based on a speculative concern that Defendants will identify and utilize an expert in connection with their *responding*, not opening, *Markman* submission, and that Plaintiffs will not have an opportunity to depose such an expert under the Court's Scheduling Order and the Patent Rules. As a result, Plaintiffs ask the Court to alter the Rules to provide for the filing of opening *Markman* briefs, responding *Markman* briefs 30 days later, *then* the commencement of discovery, *then* the filing of reply *Markman* briefs.

The rules contemplate two briefs with expert discovery to occur between the first and second briefs. Plaintiffs proposal rewrites the Patent Rules claim construction provisions to allow what amounts to the fully allotted amount of briefing, then the commencement of expert-related discovery, then an additional reply brief -- all based on their concern that the Defendants may attempt to utilize an undisclosed expert in connection with their eventual responding *Markman* submission.

11. Plaintiffs' proposed amendment to the scheduling order is rejected at this time. Plaintiffs concerns are premature and do not warrant an amendment of the scheduling order. Their concern appears based on the fact that Defendants have not designated an expert but have, unilaterally, "reserved the right" to name one at a later date. However, there is generally no "reserving" of expert witnesses in patent cases. The Patent Rules contemplate the disclosure of expert witnesses and their general testimony at two stages -- when the preliminary claim construction and extrinsic evidence disclosures are to occur pursuant to L. Pat. R. 4.2 (in this case, November 6, 2009); and when the Joint Claim Construction and Prehearing Statement is filed with the Court (here, December 7, 2009). The latter disclosures, i.e., those that accompany the Prehearing Statement, extend to experts' opinions both in support of a parties' own proposed construction *and* those in opposition to their adversary's proffered construction. See L. Pat. R. 4.3(b). At that point, all expert testimony should be known, or at least discernable, and there is no obvious basis for holding back or "reserving" additional expert testimony. Under the Rules,

the Plaintiffs in a Hatch-Waxman case should not ordinarily first learn about an expert's testimony in a responding *Markman* submission. See, e.g., L. Pat. R. 4.3(b) (requiring disclosure of expert witnesses testimony both in connection with a party's own construction and in opposition to that of its adversary). Defendants have apparently not decided to designate an expert witness at this point. Plaintiffs' concerns are premature and unfounded and do not justify the amendment sought. First, it would require this Court to conclude that Defendants have not waived their right to rely on an expert in connection with claim construction.<sup>4</sup> Second, Defendants have yet to actually take the step of attempting to rely on an expert. The Court will not alter the claim construction schedule to address issues that have not yet occurred and may not occur at all. The parties can be assured that the Court will prevent any party from being unfairly prejudiced.

12. Finally, Defendants argue that Plaintiffs' expert disclosures are deficient, and that the Court should preclude Plaintiffs from relying on an expert in connection with their claim construction submissions. From the limited information provided in the recent dueling letters, the Court disagrees. Plaintiffs have identified their expert, Dr. McGinty. They have identified the claims in dispute and that Dr. McGinty will provide testimony on each disputed term consistent with a person of ordinary skill in the art. See Pls.' Letter dated January 14, 2010, at 3 & Ex. B. While Plaintiffs' descriptions seem somewhat bareboned, the Court is not convinced that they provide insufficient notice of Plaintiffs' expert, the claims he will provide testimony

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Defendants here have apparently chosen not to identify a rebuttal expert witness based upon their own view that Plaintiffs' disclosures are inadequate and do not afford them the opportunity to determine whether a rebuttal expert is necessary. As a result, they have purported to "reserve the right" to file an expert declaration at a later time. The Local Civil Rules apply to patent cases. See L. Pat. R. 1.2. In the event the Defendants believed Plaintiffs' expert disclosures were inadequate, the proper course would have been to follow Local Civil Rule 37.1, meet and confer, and raise the issue with the Magistrate Judge.

with respect to, and the general nature of his testimony. In addition, the expert's complete opinions will be contained in his declaration and can be the subject of discovery as set forth in the Patent Rules, presumably ameliorating any prejudice. Moreover, the exclusion of important evidence is an extreme sanction employed only in the most drastic circumstances. E.g., Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-05 (3d Cir. 1977), overruled on other grounds by, Goodman v. Lukens Steel Co., 777 F.2d 113 (3d Cir. 1985), aff'd, 482 U.S. 656 (1987). No such showing is alleged in this case.

13. Nothing in this Opinion should be read to preclude Defendants from attempting to designate an expert witness during the claim construction process. That issue was not briefed, and it is not before the Court. In the event further issues arise, the parties should confer in accordance with the Court's Local Civil Rules and raise the issue with the Undersigned immediately.

14. For the reasons set forth above, Plaintiffs' request for a modification of the claim construction schedule is **denied without prejudice**. All dates in the Court's pre-trial scheduling order dated October 20, 2009, remain in full force and effect. Defendants' request to preclude Plaintiffs from relying on expert testimony in connection with the issue of claim construction is **denied**.

15. A separate Order implementing this Opinion will be entered.

/s/ Mark Falk  
**MARK FALK**  
**United States Magistrate Judge**

Dated: January 22, 2010